MAR - 1 2001

K003705

510(k) SUMMARY
PhotoMedex, Inc.
XTRAC Excimer Laser System, model AL7000

1. GENERAL

- *Submitter:* PhotoMedex, Inc.
  2431 Impala Drive
  Carlsbad, CA 92008
- *Contact Person:* Al Memmolo
- *Date Prepared:* November 30, 2000

2. DEVICE NAME

- *Classification name:* Laser surgical instrument for use in general and plastic surgery and in dermatology (21 CFR §878.4810)
- *Common or usual name:* XeCl excimer laser
- *Trade or proprietary name:* XTRAC Excimer Laser System, model AL7000

3. PREDICATE DEVICES

Ultraviolet Lamps

- HOUVA II, Phototherapy System
  National Biological Corporation
  510(k) number: K885026
- UviSol, Phototherapy System
  National Biological Corporation,
  510(k) number: K934808

Excimer Laser

- XTRAC Excimer Laser System, model AL7000
  Photomedex, Inc.
  510(k) number: K992914

4. DEVICE DESCRIPTION

The XTRAC Excimer Laser System is a complete self-contained compact laser light source, which utilizes a XeCl gas mixture to generate ultraviolet light at wavelength of 308 nm wavelength. The laser system consists of a keypad and display, a fiberoptic delivery system, a footswitch, and a handpiece. The laser is enclosed in a protective interlocked housing.

5. INTENDED USE

The intended use is UVB phototherapy for psoriasis and vitiligo.

6. SUBSTANTIAL EQUIVALENCE

Narrow-band UV-B 311 alone has been shown by Westerhof and Nieuweboer-Krobotova[1] to be just as effective in the treatment of vitiligo as PUVA. The results of this study showed that 46% of patients in the PUVA showed repigmentation after 4 months, whereas 67% of patients in the narrow-band UV-B group showed repigmentation. Adverse events related to psoralen gel application including erythema, scaling and itching were not encountered by the group that received UV-B. The authors concluded, "the treatment of vitiligo with narrowband UV-B twice weekly is a safe and effective treatment." UVB generated by the PhotoMedex Excimer Laser System was determined by the FDA to be substantially equivalent to narrow-band UVB (311nm) produced by predicate UV lamps.

The intended use for the **PhotoMedex XTRAC Excimer Laser System** is within to that of the predicate ultraviolet lamps. Both device types share the same methods and mechanisms of treatment.

The XTRAC Excimer Laser System, model AL7000 was cleared per 510(k) number: K992914.

7. PRODUCT PERFORMANCE TESTING

Testing conducted on the XTRAC Excimer Laser System includes conformance to all relevant international EN 60601 / IEC 601 series of standards and applicable laser standards including UL 2601.

8. CONCLUSIONS

Based on the same intended use as ultraviolet lamps, the identical technological characteristics of the excimer lasers, and the and performance data, PhotoMedex believes that the XTRAC Excimer Laser System is substantially equivalent to the predicate devices.

1. Westerhof W, Nieuweboer-Krobotova L. Treatment of vitiligo with UV-B radiation vs topical psoralen plus UV-A. Arch Dermatol 1997, 133:1525-1528.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 1 2001

Mr. Bob Rose
Manager of Regulatory Affairs
PhotoMedex, Inc.
2431 Impala Drive
Carlsbad, California 92008

Re: K003705
Trade Name: XTRAC Excimer Laser System, Model AL7000
Regulatory Class: II
Product Code: GEX
Dated: November 30, 2000
Received: December 1, 2000

Dear Mr. Rose:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003705

Device Name: ***XTRAC Excimer Laser System, model AL7000***

Indications for Use:

UVB Phototherapy for psoriasis and vitiligo

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter-Use _____
(Per 21 CFR 801.109)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K003705